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FORMULATION AND EVALUATION OF FELODIPINE ORAL DISPERSIBLE TABLET

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ABSTRACT

In the current study, the anti-hypertensive medication felodipine or dispersible tablets that are employed via direct compression method are modelled and evaluated in vitro using a variety of super disintegrants. Guar gum, sodium starch glycolate, and Croscarmellose sodium were used as super disintegrants in the preparation of the dispersible felodipine tablet. Other excipients included mannitol, talc, magnesium stearate, microcrystalline cellulose, and others. Precompression characteristics of the prepared dispersible tablet, such as bulk and tapped density, angle of repose, cars index, etc., were assessed. The range contains all of the parameters. Studies on post compression characteristics such as hardness, thickness, disintegration time, dissolution, and stability were also conducted. Out of all the formulations, the F1 formulation was determined to be the most optimised. The F1 formulation had a 15-second disintegration time and a 15- minute drug release percentage of around 100.047%. The stability investigations yield excellent results as well

Keywords: Oral dispersible Tablet, Felodipine, Direct compression.

1. INTRODUCTION

Orally disintegrating tablets are sometimes referred to as orodispersible tablets, mouth dissolving tablets, fast disintegrating tablets, rapid dissolving tablets, porous tablets, and rapid melts. Despite all of the aforementioned terms, the USP has designated these dose forms as ODTs.(1) Orodispersible tablets are those that dissolve easily in the mouth before being swallowed, according to the European Pharmacopoeia. (2)

Objectives

- Enhancing bioavailability
- To improve patient adherence
- Preventing first pass metabolism
- For improved stability (3)

Ideal properties of Orodispersible tablets

- Easy to transport
- Simple manufacturing process
- ODT's are less sensitive to the environmental conditions such as temperature and pressure
- Tablets designed to be dispersed should have a high drug loading capacity.
- The method should be compatible with already-in-use processing and packaging equipment, be stable, and have a low manufacturing cost.(4)

Materials and Equipment's

Table.1

Sr.No.	Equipment's
1.	Uv visible* Spectrophotometer
2.	Weighing Balance
3.	USP Type II Dissolution Test Apparatus
4.	USP Disintegration Test Apparatus
5.	Digital pH meter
6.	FTIR Spectrophotometer
7.	8 Station Rotary Tablet Compression Machine
8.	Hardness Tester
9.	Roche Friability Tester

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Sr.No.	Drug and Excipients	Quantity (% w/v)
1.	Felodipine	5
2.	Guar gum	9
3.	Crosscarmellose Sodium	7.5
4.	Sodium Starch Glycolate	12
5.	Mannitol	20
6.	Microcrystalline Cellulose	93.5
7.	Talc	1.5
8.	Magnesium Stearate	1.5
	Total	150 mg

2. RESULT AND DISCUSSIONS

Melting Point

The melting point of felodipine was found 144°C.(5) **pH**

The pH of felodipine was found to be 6.81 which were similar to its standard value i.e. 6.8(6) **Determination of λ max of Felodipine λmax of Felodipine in Methanol**

The absorption spectra in the range of (200-400nm) were obtained for felodipine in methanol.

The drug exhibited an absorption maximum of 362nm.(7)

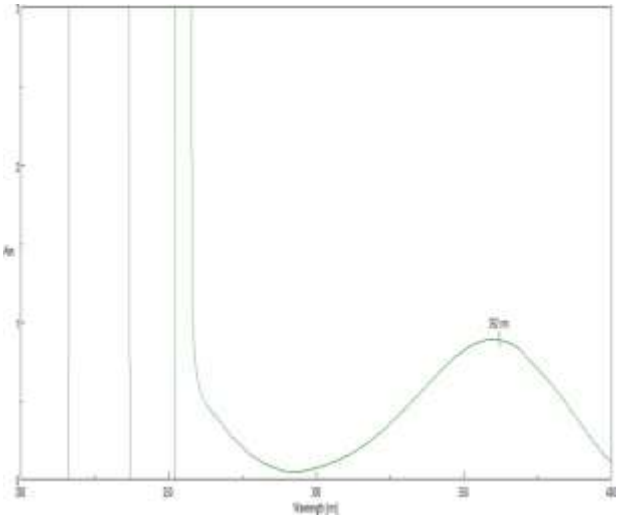

Fig.1

Solubility Studies

The solubility study of felodipine was carried in distilled water and was found to be; **Saturated Solubility of felodipine in distilled water:** 0.00112mg/ml (8)

Calibration curve of Felodipine in Methanol (362nm, R^2=.09993) Table No Calibration curve of Felodipine in Methanol

Table.2

Sr.No.	Conc.(µg/ml)	Absorbance
1	0	0
2	2	0.1409
3	4	0.2862
4	6	0.4291
5	8	0.5699
6	10	0.7125

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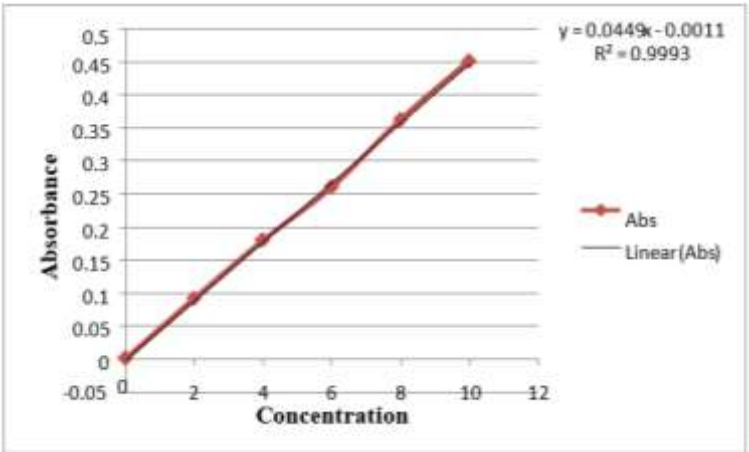

Fig. 2 No. Calibration curve of Felodipine in Methanol Drug-excipients compatibility study by FTIR API(Felodipine)

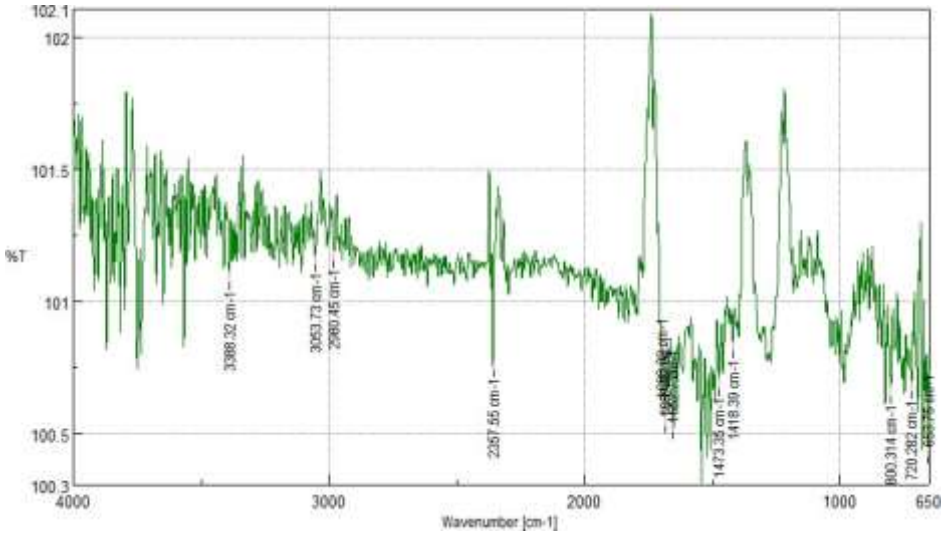

Fig. No. 3 FTIR of pure Felodipine

Pre-compresssion Parameters

Table.3

Formulation	Bulk Density (gm./cm²)	Tapped Density (gm./cm²)	Carr's Index (%)	Hausners Ratio	Angle of Repose (Θ)
F1	0.41	0.50	18.00	1.21	29.27
F2	0.49	0.58	15.51	1.18	30.21
F3	0.41	0.49	16.32	1.19	34.56
F4	0.58	0.69	15.94	1.18	30.32
F5	0.52	0.63	17.46	1.21	36.89

Post Compression Parameters

Table.4

Formulation	Hardness(kg/cm²) n=6	Friability(%) n=10	Thickness(mm) n=4	Diameter(mm) n=4	Weight Variation (%) n=20
F1	2.8	0.29	3.40	7	1.49
F2	2.9	0.31	3.51	7	2.63
F3	3.1	0.33	3.56	7	4.61
F4	3.4	0.36	3.43	7	2.94
F5	3.3	0.37	3.45	7	5.79

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Post compressional Parameters

It includes Drug content, wetting time and water absorption ratio of tablet formulations.

Table No.5 Post compressional Parameters (Drug content, and Water absorption ratio)

Formulation Code	Drug Content (%)	Water Absorption Ratio (%)
F1	99.63	3.26
F2	94.2	4.13
F3	96.4	3.86
F4	91.7	6.13
F5	93.9	5.20

Drug Content

Drug content is mainly used to calculate the amount of pure drug present in each tablet. It ranged from 91.7 to 99.63%. F1 formulation shows highest value of drug content which is

99.63% respectively. Table number 30 shows % drug contents. ((9)

Water absorption ratio

It includes ratios from 3.26 to 7.53 % of water absorption. Table 30 showing information of water absorption ratio(10)

Wetting Time

From the results it is found that the wetting time of formulations are not more than 62 sec. It falls in between 25 to 62 seconds.(11) F1 formulation shows wetting time of about 25 seconds. Table number 31 shows data of wetting time. (12)

Table.6

Formulation Code	Wetting time (sec)
F1	25
F2	31
F3	36
F4	44
F5	47

In-vitro Dispersion Time

In this a tablet was added to 10 ml of phosphate buffer solution of pH 6.8 at 37±0.5 ℃. Then time required for a tablet to form complete dispersion was measured. (13)

Table No.7 In-vitro Dispersion Time (F1-F9)

Formulation Code	In-vitro Dispersion Time (sec)
F1	18
F2	21
F3	26
F4	24
F5	35

Disintegration Time

Table No. 33 shows Disintegration Time of tablet formulations. Disintegration Time of tablets is ranges from 15 to 45 sec. (14,15)DT of all formulations is listed below; Out of all the formulations F1 formulations containing guar gum (6%), crosscarmellose sodium (5%), and sodium starch glycolate (8%) respectively, shows a rapid DT which is only 15 seconds (16,17)

Table.8

Formulation code	Disintegration Time (Sec)
F1	15

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F2	19
F3	22
F4	29
F5	33

In-vitro drug release studies

Table No.9 Cumulative % drug release of Orodispersible Tablet of Felodipine (F1-F4)

Time(sec)	F1	F2	F3	F4
0	0	0	0	0
5	88.40	88.42	88.40	77.00
10	94.38	94.45	94.35	84.86
15	100.047	96.43	95.03	91.59

In-vitro drug release studies were carried out by using USP Dissolution test apparatus at 50 Rpm. Dissolution profiles of tablet formulations from F1 to F4 were shown in table number.(18,19) F1 formulation contains highest concentration of disintegrtats i.e. guar gum

(6%), Crosscramellose sodium (5%), and sodium starch glycolate (8%) respectively.(20,21)

3. CONCLUSION

The current study reveals that a great attempt has been made in order to formulate and study the drug release behavior of Felodipine Orodispersible tablets with improved rapid release and bioavailability.

From all this experimental work we can conclude;

- A drug can be easily analyzed by using UV-Visible spectrophotometry. Felodipine shows maximum absorption at 362nm in methanol. The value of linear regression coefficient was found to be 0.999, which indicates linear relationship between absorbance and concentration.
- IR studies reveals that their no significant interaction between the formulation components.
- From experimentation we can say that as the concentration of superdisintegrants increases there is increase in disintegration time and drug release behavior.
- Various combinations of superdisintegrants have a great impact on Disintegration time and drug release behavior as it improves both of them.
- The formulated tablets showed compliance for various physicochemical parameters such as disintegration, drug content and in-vitro drug release.

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